DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-029/S-006

Schering Corporation
2000 Galloping Hill Rd
Kenilworth, NJ 07033

Attention: Mary Jane Nehring
Senior Director, Market Products Supports

Dear Ms. Nehring:

Please refer to your supplemental new drug application dated April 25, 2003, received April 25, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Temodar (temozolomide) Capsules 5, 20, 100, and 250 mg.

We acknowledge receipt of your submission dated March 18, 2004, received March 23, 2004.

This supplemental new drug application provides for revised safety measures taken in response to the Agency's April 29, 2003 correspondence regarding reports of fatal medication errors involving Temodar.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the editorial revision listed below.

1. Container Labels (5's and 20's) and Carton Labeling (1 x 5's and 1 x 20's)

   Since the 20 mg and 250 mg strengths were previously confused, DMETS was concerned that the proposed colors used to distinguish these strengths were too close in appearance (brown and black). However, we have learned through this submission that the color utilized to designate the product strength on both the container label and carton labeling correspond to the respective color of the capsule ink imprint. Thus, at this time FDA will not request any further color differentiation between the 20 mg and 250 mg capsules. However, if errors are reported between these strengths post implementation of the current revisions, we reserve the right to request further differentiation at that time. All other revisions to the container labels and carton labeling are acceptable.

2. Draft Healthcare Professional Letter

   Page 1, Temodar Capsule Strength Chart – Insert a space between the whole number (e.g., 5, 20, 100, and 250) and the unit of measure (mg). For example: 5 mg rather than 5mg.

3. Patient Package Insert

   This is a patient package insert and not a medication guide. Thus all references to "Medication Guide" must be deleted from this document.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the submitted labeling, patient package insert and, immediate container and carton labels submitted March 18, 2004. These revisions are terms of the approval of this application.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-029/S-006." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Sean Bradley, R.Ph., Regulatory Project Manager, at (301) 594-5770.

Sincerely,

{See appended electronic signature page}

Richard Pazdur, M.D.
Director
Division of Oncology Drug Products
Center for Drug Evaluation 1
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Richard Pazdur

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